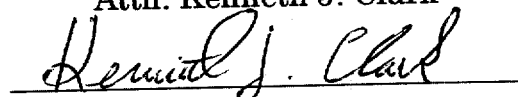


FEB 16 2001

**PREMARKET NOTIFICATION 510(k) SUMMARY**

June 30<sup>th</sup>, 2000

Total Water Treatment Systems  
4806 East Broadway  
Madison, Wisconsin 53716  
Attn: Kenneth J. Clark



608/221-2236

800/929-2236

608/221-7328(fax)

**WATER PURIFICATION SYSTEM FOR HEMODIALYSIS**

Regulatory Classification:

Class II

CFR 876.5665(a)

Product Code:

78 FIP

Total Water Treatment Systems(TWTS) is applying for a 510(k) premarket notification for our "Water Purification System for Hemodialysis". The following is a summary of our submission document. The regulatory classification is class II CFR 876.5665(a), Product Code 78 FIP. The device we are claiming substantial equivalence to is marketed by U.S. Filter. The registration number for this device is K980182, U.S. Filter Water Purification System, Regulatory Class: II, 21 CFR 876.5665/Procode: 78 FIP.

The TWTS water purification system for hemodialysis will be used with a hemodialysis system. The water purification system will remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate, bicarbonate, acetate and sterilant for dialyzer reprocessing. The purified water will also be used in the equipment disinfection process, equipment rinsing and any other application the clinic/customer deems appropriate. This system will meet all the requirements put forth by the United States Food and Drug Administration(FDA) and the Association for the Advancement of Medical Instrumentation(AAMI) and any other laws that may apply.

The TWTS water purification system utilizes no new water purification techniques. Reverse osmosis(RO), deionization, carbon filtration

and water softening are the core to this system. The predicate device system we are comparing to, utilizes the exact same core water purification principles. The following is a comparison summary of the TWTS water system and the predicate device.

TWTS and U.S. Filter both utilize a water softener made of materials which is "NSF" and /or FDA approved. U.S. Filters' softener is installed with a single regeneration tank and electrically interlocked to shut down the RO unit operation during the softener regeneration cycle. TWTS softener is installed in a duplex-twin alternating fashion to provide softened water to the system 24 hours a day. While one regeneration tank is in a regeneration cycle the other regeneration tank is on line providing soft water to the system. This will prevent the possibility of softener regeneration or a salt dump into the water purification system during a patient shift. This also eliminates the need to shut down the RO unit for softener regeneration.

Carbon filtration is utilized by both TWTS and U.S. Filter to filter out chlorine and chloramines from the water. Both systems use two carbon filters in a series configuration with test ports installed after each filter. A minimum total contact time of 10 empty bed contact time minutes are incorporated into both designs as recommended by the FDA for chlorine and chloramine removal. Both TWTS and U.S. Filter recommend the chlorine and chloramine levels be checked before each patient shift. Hard plumbed bypass piping of the carbon tanks is not allowed in either system. Both systems will utilize an activated carbon with an Iodine number of 900 or greater. U.S. Filter uses in line carbon regeneration filters. Since carbon is an organic compound and bacteria naturally grows in it TWTS uses disinfected portable exchange carbon tanks and new media. U.S. Filter uses a single carbon filter in its single patient dialysis system. TWTS always uses a dual carbon filter in series in every dialysis water system installed, including single patient systems.

TWTS and U.S. Filter both use a RO prefilter with a noncotton filtration media. Dual prefilters are essential in all Direct feed applications where the RO cannot be shut down during patient shifts. U.S. Filter recommends using a RO prefilter that is a 1 or 5 micron polypropylene string wound or melt blown cartridge. TWTS uses a nominally rated 5 micron polypropylene melt blown cartridge RO prefilter.

TWTS and U.S. Filter use only reverse osmosis(RO) units that are registered medical devices. Modifications to the standard registered medical RO system is strictly forbidden without proper supporting documentation and authorization. The RO units that TWTS utilizes must have connections for external remote alarms to be installed adjacent to the dialysis treatment area. The use of an external remote alarm provides the care giver and patient with a constant water quality status and relays any equipment related problems with the RO unit.

TWTS and U.S. Filter use a RO storage tank that is dish bottom domed top completely sealed style. The RO storage tank has a hydrophobic nominal 0.2 micron filter to prevent airborne bacteria from entering the tank, Vent filters should be changed once per year. U.S. Filter's storage tank is

made of polypropylene, polyethylene or FDA approved fiberglass. TWTS RO storage tank will be made out of FDA approved fiberglass only.

TWTS and U.S. Filter use product water recirculation pumps sized for adequate flow and pressure. The recirculation pump will deliver preferably a minimum of 3 feet per second velocity at the lowest flow point of the system. For Direct feed RO systems a minimum velocity of 1.5 feet per second at the end of the return to the RO inlet is required. Recirculation pumps should be installed in parallel. U.S. Filter alternates parallel installed pumps weekly to reduce stagnant water bacterial conditions within the idle pump. TWTS alternates parallel installed pumps daily and has continuous flow through the pump while idle. This reduces any temporary deadlegs between pumps and reduces the chance of water bacteria problems.

TWTS and U.S. Filter use mixed bed worker-polisher deionization tanks in a series configuration. U.S. Filter has a resistivity meter to monitor the water quality coming out of the final mixed bed deionization tank. TWTS installs a NIST traceable temperature compensated resistivity meter to monitor the quality of water exiting the worker mixed bed deionizer and the polisher mixed bed deionizer. Both readings will be wired into a remote alarm system located adjacent to the dialysis treatment area. The worker mixed bed deionizer will alarm when the water quality at the output of that tank drops below 1 M ohm and alarms visually at the remote monitoring panel. The polisher mixed bed deionizer will alarm when the water quality at the output of that tank drops below 5 M ohm. TWTS will install single bed cation and anion deionization tanks prior to the mixed bed deionizers whenever possible. TWTS utilizes portable exchange deionization tanks as a final product water in-line polisher that can also be used as a temporary bypass system in case of RO unit malfunction. By doing this TWTS will avoid any deadleg lines coming from backup deionization tanks that could harbor harmful bacteria.

TWTS and U.S. Filter incorporate final bacterial removal filters into all designs. Final filters should be absolute rated. Nominally rated filters will not be used as the final filter. Final bacteria removal filters must be installed after a UV light, if a UV light is utilized. U.S. Filter uses final bacteria removal filters that are 0.2 or 0.1 micron filters. TWTS uses final bacterial removal filters that are hollow fiber 0.1 or 0.05 micron endotoxin filters to provide better bacteria and endotoxin removal.

TWTS and U.S. Filter incorporate emergency equipment bypass lines and valving that is clearly labeled and tagged. Instructions for usage will be included with the water system and staff in service will be provided to the clinic/customer by TWTS. The use of dead legged bypass piping will be avoided. Carbon filters will not have hard plumbed bypass lines. U.S. Filter emergency equipment bypass utilizes a dry bypass system. This system uses breakable unions and isolation valves at the end of each bypass line so that stagnant water will not be present in the line in the event of an emergency bypass condition. TWTS emergency equipment bypass is a wet bypass system. In this system the bypass valve is installed with no more than one

and one half pipe diameters length on either side of the bypass valve to avoid water stagnation. The use of dead leg bypass piping is unacceptable.

TWTS water distribution piping system will be configured with no deadlegs longer than 2 pipe diameters. U.S. Filters' water distribution piping system will be configured with no deadlegs longer than 6 pipe diameters. U.S. Filter installs sanitization/sanitant introduction valve(s) or introduction port must be incorporated to allow chemical injection of sanitants to allow sanitization of the RO system and storage tanks and distribution. TWTS sanitization/sanitant introduction sites will be through the deionization connections or through the top of the storage tank. By using one of these two sites for sanitant introduction TWTS avoids having any additional deadleg bypass valving installed into the original piping system and this further avoids water stagnation.

Included in this document is labeling that is applied to the components of the water purification system for hemodialysis. AAMI water purification standards are also included with an actual water quality analysis and Total Organic Carbon analysis from an existing water purification system for dialysis. Diagrams of the direct, indirect and single patient water purification systems are included along with a diagram of a remote monitor alarm panel. A user manual for the hemodialysis water system is included as the last item of this document.

In summary, the TWTS water purification system and the U.S. Filter predicate device system are very similar to one another. The core water purification components and technology are exactly the same. The differences are in the application of the bypass equipment and the additional water quality alarm equipment TWTS has incorporated into all our new water purification systems for hemodialysis. Most of the differences in these two systems are derived from the fact TWTS is in a constant attempt to provide the best water quality and safest possible system to the public.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 16 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kenneth J. Clark  
Sales/Engineer  
Total Water Treatment Systems, Inc.  
4806 East Broadway  
MADISON WI 53716

Re: K002045  
Water Purification System for Hemodialysis  
Received: November 20, 2000  
Regulatory Class: II  
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Clark:

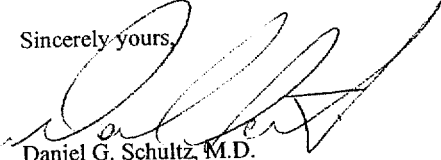
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002045

Device Name: Water Purification System for Hemodialysis

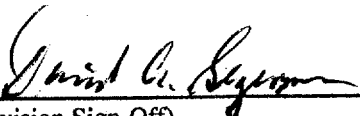
Indications For Use:

The Total Water Treatment Systems hemodialysis water purification system is intended to be used in the purification of water for use in hemodialysis outpatient and acute settings. The purified water will be used with a hemodialysis system. The water purification system will remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate, bicarbonate, acetate and sterilant for dialyzer reprocessing. The purified water will also be used in the equipment disinfection process, equipment rinsing and any other application the clinic or customer deems appropriate.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K002045

(Optional Format 3-10-98)